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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,335	10/09/2001	Barbara A. Soltz	P00594-US	6202

3017 7590 11/24/2003

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EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,335

Applicant(s)

SOLTZ ET AL.

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 6 is objected to because of the following informalities: Derivatized is not a word. The examiner assumes the applicant meant derived. Applicant should be appropriate corrections.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3, 4, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Poppas US 5,713,891. Poppa discloses in column 7 a method of bonding tissue by placing tissue 'A' in close contact with tissue 'B'. The adhesive can be composed of collagen (col 5, line 4). The protein for the adhesive can be in concentrations of 50% (col. 8, line 60-65). It is inherent that although albumin is described to be in the concentration above, any of the proteins disclosed in the application such as fibrinogen or collagen can be made to same concentration. The applicant might wish to note that US references 5164139, 6310036, 2002/0022588, and 2002/0098222 also disclose collagen in concentrations circa 30-80% for use as a tissue adhesive. The step of exposing the adhesive to EM is recited throughout the Poppa reference (col. 7, 15-30 or col. 8 60-65). The EM radiation is in the form of a laser. The laser is controlled by a temperature sensing means (col. 4, 10-23). Collagen being a protein will inherently have functional carboxyl groups with their associated conjugate acid-base pairs as explained by the well-known Brønsted-Lowry theory of acid-base reactions. The adhesive is a solid.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poppas '891 in view of Bass et al. 5209776. Poppas '891 discloses the use of a long list of possible irradiating means but does not mention using infrared. Bass et al. '776 teaches collagen welding as well as mentions infrared laser may be used to heat and denature the collagen. At the time of the invention it would have been obvious to one having ordinary skill in the art to heat the collagen with the Bass et al. '776 infrared laser because infrared lasers are capable of denaturing the collagen.

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poppas '891 in view of Sawyer 5156613. Poppas discloses the collagen adhesive of claim 5, but does not disclose the use of the cyanoacrylate. The use of a cyanoacrylate is advantageous as it immediately secures the collagen to the wound site. This concept is taught by Sawyer '895 (col. 10, 66). At the time of the invention it would have been obvious to one having ordinary skill in the art to add the Sawyer '895 cyanoacrylate to the Poppas collagen adhesive because Sawyer teaches the cyanoacrylate can bind the collagen to the tissue.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poppas '891. Poppa discloses the laser can be used to weld the collagen at temperatures of 50 – 90 degrees Celsius. At the time of the invention, it would have been obvious to one of ordinary skill in art to use the laser to weld the collagen at a temperature of 55- 60 degrees Celsius since it has been

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held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
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11/14/03



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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